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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,903	01/28/2002	Timothy Robert Hurley	A0000513-01-DRK	7220

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EXAMINER
KHARE, DEVESH

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,903	HURLEY ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☒ Interview Summary (PTO-413) Paper No(s). 3 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election of Species

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits.

Applicant is advised that a complete reply to this requirement must include an identification of the species that is elected and a listing of all claims readable thereon. Applicant is entitled to consideration of claims to a reasonable number of disclosed species in addition to the elected species provided all the claims to each additional species are written in dependent form or otherwise include all the limitation of an allowed generic claim as provided by 37 CFR 1.141. Applicant's reply must include an identification of such additional species along with a listing of the claims readable on each additional species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. if claims are added after the lection, applicant must indicate which are readable upon elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the invention.

A telephone call was made to David Kurlandsky on 6/18/03 to request an oral election of species of a pregabalin conjugate containing a hexose-hexose, hexose-furan or furan group. Applicant has elected the hexose-hexose group in the pregabalin conjugate in claims 1-7.

The pregabalin conjugates containing hexose-furan or furan group in claims 1-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 1-7 are currently pending in this application. An action on the merits of claims 1-7 is contained herein below.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pande (U.S. Patent 6,359,005) in view of Wirth et al. (J. Pharm. Sci.,87(1), 31-39, 1998).

The claims 1-7 are directed to pregabalin lactose conjugates, their pharmaceutical formulation and a method for treating a subject having a central nervous

system disorder or disease by administering to the subject a pharmaceutically effective amount of a compound of claim 1.

Additional claim limitations claimed include the central nervous system disorder or disease such as seizure or anxiety and a pharmaceutical formulation comprising at least one compound of pregabalin lactose conjugate and a pharmaceutically acceptable carrier, excipient, or diluent thereof.

Pande teaches the pregabalin, its derivatives, and pharmaceutically acceptable salts for use in the treatment of mania and bipolar disorder (see abstract). In column 3, lines 14-17, the pharmaceutical compositions of pregabalin or its salts with a pharmaceutically acceptable carrier are disclosed. In column 2, a line 47-54, the use of pregabalin in the treatment of patients suffering from anxiety is disclosed. In column 3, lines 63-67, the use of pregabalin in the treatment of patients suffering bipolar disorder especially the epilepsy is disclosed. Pande also disclose suitable pharmaceutical carriers; including the pharmaceutical diluent lactose (see col. 3, 22-24). While the Pande's use of pregabalin and derivatives in the treatment of anxiety or epilepsy are closely analogous to the applicant's compounds, Pande's pregabalin compounds and compositions differ from applicant's pregabalin lactose conjugates and compositions in that the pregabalin compounds are not conjugated with lactose.

Wirth et al. teach that the drug which are secondary amines undergo the Maillard reaction with lactose and lactose is used as the most common excipient in the formulations of fluoxetine HCl (see abstract). Applicants in example 5 disclose that the

pregabalin undergoes a Maillard reaction to form conjugates with lactose in formulated product. Wirth et al. disclose that the reducing carbohydrate such as lactose is substrate for the Maillard reaction (see page 31, bottom of first col. and scheme 2 on page 33). Wirth et al. disclose that the lactose is widely used as diluent for capsules and tablets due to its low price, high purity, and excellent compression and stability characteristics and its ability to undergo Maillard reactions to produce formulation (see page 31, sec. col., sec. para). It is noted that Wirth et al. does not provide specific disclosures regarding the pregabalin lactose conjugate.

Therefore, one of ordinary skill in the art would have found the applicants claimed pregabalin lactose conjugates, their pharmaceutical formulation and a method for treating a subject having a central nervous system disorder or disease by administering to the subject a pharmaceutically effective amount to have been obvious at the time the invention was made having the above cited references before him. Since Pande teaches the pregabalin, its derivatives, and pharmaceutically acceptable salts for use in the treatment of anxiety or epilepsy (nervous system disorder), and Wirth et al., teach the excellent compression and stability characteristics of lactose and its ability to undergo Maillard reactions to produce formulation, one skilled in the art would have a reasonable expectation for success in combining both references to accomplish the pregabalin lactose conjugate, its pharmaceutical composition and their use in the treatment of anxiety or epilepsy. The motivation for doing so is provided by Pande,

which suggests the use of pregabalin in the treatment of anxiety or epilepsy because of the nontoxic nature of the compound, ease of preparation and the ease of administration of the drug (see col. 3, lines 55-60).

State of the Art References

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bruna et al. (U.S. Patent 6,488,964)- discloses the process for manufacturing coated pregabalin particles.

Mylari (U.S. Patent 6,544,988)- discloses the pharmaceutical compositions containing GABA agonist.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
June 29,2003